K043331

MAR 4 - 2005

Pg. 1 of 2

MTC *Media Trade Corporation*

11820 Red Hibiscus Drive – Bonita Springs, FL 34135
Tel (239) 948-2001 – Fax (239) 948-2002
E-mail: mediatradecorp@gmx.net

510(k) Summary

Submitter's Name:	Guenter Ginsberg Media Trade Corporation
Address:	11820 Red Hibiscus Drive Bonita Springs, FL 34135
Phone:	(239) 948-2001
Fax:	(239) 948-2002
E-mail:	mediatradecorp@gmx.net
Contact:	Guenter Ginsberg
Date of Summary:	May 7, 2004
Trade Name:	Digital Forehead Thermometer FS-100
Classification:	Thermometer, Clinical, Electronic Product Code: FLL Regulation Number: 880.2910 Class: II Panel: 80 (General Hospital)
Predicate Devices:	Exergen Corporation Temporal Scanner Thermometer K 011291 (Predicate)

K043331
Pg 2 of 2

Device Description:

The **Digital Forehead Thermometer FS-100** is a hand held, battery operated device that measures the skin temperature of the skin over the temporal artery. Operation is based on measuring the natural thermal infrared radiation emitted from the surface of the skin over the temporal artery.

Intended Use:

The **Digital Forehead Thermometer FS-100** is an infrared thermometer intended for the intermittent measurement of human body temperature of people of all ages.

Technological Characteristics:

The **Digital Forehead Thermometer FS-100** has the same general design and performance characteristics as the predicate device from Exergen Corpporation. The main difference is the physical size, shape and weight.
The **Digital Forehead Thermometer FS-100** has the same intended use, general design and incorporates similar materials and components, hence should therefore raise no new questions of safety and effectiveness.
This submitter concludes that the **Digital Forehead Thermometer FS-100** is therefore substantially equivalent to the predicate device from Exergen.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 4 - 2005

Hubdic Company Limited
C/O Mr. Guenter Ginsberg
Official Correspondent
Media Trade Corporation
11820 Red Hibiscus Drive
Bonita Spring, Florida 34135

Re: K043331
Trade/Device Name: Digital Forehead Thermometer FS-100
Regulation Number: 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: February 2, 2005
Received: February 7, 2005

Dear Mr. Ginsberg:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

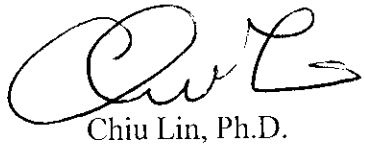
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): **K043331**

Device Name: Hubdic Co. Ltd., **Digital Forehead Thermometer FS-100**

Indications For Use:

This device is an electronic clinical thermometer using an infrared sensor to detect body temperature from the skin surface over the temporal artery on the forehead. It is intended for people of all ages.

Prescription Use _____ AND/OR Over-The-Counter Use ✓
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Vicki Hubbard for Anthony Watson

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

(510(k) Number) K043331